

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

C.A. No. 24-1025-JLH

HETERO USA, INC., HETERO LABS LTD.,  
and HETERO LABS LTD. UNIT-VI,

Defendants.

**~~PROPOSED~~ STIPULATED PROTECTIVE ORDER**

WHEREAS discovery in this Action may involve the disclosure of certain documents, things, and information in the possession, custody, or control of Plaintiff Ingenus Pharmaceuticals, LLC (“Ingenus”) and Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (“Hetero”), or nonparties that constitute or contain trade secrets or other confidential research, development, or proprietary business information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure;

WHEREAS such confidential information must be protected to preserve the legitimate business interests of the parties or nonparties;

WHEREAS the parties, through counsel, have stipulated to the entry of this Protective Order for the purpose of advancing the progress of this action and to prevent unnecessary dissemination or disclosure of their respective confidential information; and

WHEREAS the parties, through counsel, stipulate that good cause exists for the entry of this Protective Order pursuant to Rule 26(c) to safeguard against improper disclosure or use of confidential information produced in this action;

It is hereby ORDERED that the following provision shall govern the conduct of further proceedings in this action:

**Definitions**

1. The term “Protected Information” shall include all information that the designating party believes constitutes, discloses, or relates to the proprietary business information, processes, operations, research, technical or developmental information, production, marketing, sales, shipments, or other proprietary data or information of commercial value not generally available to the public, including, but not limited to, trade secrets. The information contained therein and all copies, abstracts, excerpts, analyses, or other writings that contain, reflect, reveal, suggest, or otherwise disclose such Protected Information shall also be deemed Protected Information. All parties shall act in good faith in designating information as Protected Information.

2. “CONFIDENTIAL” information means Protected Information designated in accordance with Paragraph 5.

3. “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information means Protected Information that is the subset of CONFIDENTIAL information designated in accordance with Paragraph 7.

4. The term “Qualified Person” shall mean:

- (a) Court and any Court personnel involved with this action;
- (b) Plaintiffs’ outside counsel, their legal assistants, and members of their support staffs;
- (c) Hetero’s outside counsel, their legal assistants, and members of their support staffs;

(d) Any independent expert or consultant who is retained by counsel solely for the purpose of assisting in this action, subject to the provisions of Paragraph 19;

(e) Photocopy services;

(f) Professional translators who are retained by the attorneys for the parties for the purposes of this litigation;

(g) Stenographic reporters, videographers, official court reporters, and their assistants who are engaged in such proceedings as are necessary for the preparation and trial of this action;

(h) Jury or trial and persons employed or retained by them solely in providing litigation support services to the parties' outside counsel law firms;

(i) Document imaging and database services and consultants retained to set up, maintain, and/or operate litigation databases for this litigation;

(j) Graphics or design consultants retained to prepare demonstrative or other exhibits for use in this action;

(k) Up to two in-house personnel for the receiving party and their respective secretarial, clerical, paralegal, and other supporting personnel who: (i) are responsible for monitoring and/or supervising this action, and (ii) do not engage formally or informally or directly or indirectly, in (A) any patent prosecution in accordance with Paragraph 19, (B) preparing submissions to FDA or a foreign equivalent concerning cyclophosphamide —except for submissions relating solely to obtaining approval or maintaining approval of the receiving party's own NDA or ANDA—unless requested by the FDA or otherwise required by law, or (C) any Competitive Decision-Making (business or strategic decisions, including marketing, financial, product development/design, and pricing decisions, on issues affecting competition) relating to

cyclophosphamide products, compositions or formulas, for the duration of this action and for two years after entry of final judgement from which no appeal may be taken (or the dismissal of this action) without first obtaining (1) consent from the Producing Party or (2) an order from the Court. Competitive Decision-Making shall be interpreted consistently with the Federal Circuit's decision in *In re Deutsche Bank*, 605 F.3d 1373 (Fed. Cir. 2010), and shall not include decision-making as an attorney related to this action;

- (i) For Plaintiff, these in-house legal personnel shall include Matthew Baumgartner, Authorized House General Counsel, Ingenus Pharmaceuticals, LLC.
- (ii) For Hetero, to be determined.
- (iii) The parties reserve the right to propose to designate additional in-house legal personnel employed by the parties at a later date.

(l) Any other person who is designated as a Qualified Person by Order of the Court or by written agreement of the parties, provided that such person completes and signs the undertaking in the form of Exhibit A.

#### **Use of Protected Information**

5. A producing part may designate any material "CONFIDENTIAL" for protection under this Protective Order where that material constitutes or discloses "CONFIDENTIAL" information. "CONFIDENTIAL" information, as that term is used herein, comprises information that the producing party in good faith contends to constitute or contain information that is: (a) confidential, sensitive, competitive, or potentially invasive of an individual's privacy interests; (b) not generally known in the context or form as known by the producing party; (c) not normally revealed to the public or third parties or, if disclosed to third parties, is such that the producing

party would require such third parties to maintain the information in confidence; and (d) information (regardless of how generated, stored, or maintained) or tangible things that qualify for protections under standards developed under Federal Rule of Civil Procedure 26(c). “CONFIDENTIAL” information includes, but is not limited to, confidential research, development, technical, commercial, or financial information, as well as other such information that the requesting party and nonparties would not have access to but for this litigation.

6. Access to any “CONFIDENTIAL” information shall be limited to Qualified Persons as described in Paragraph 4.

7. A producing party may designate any material “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” for protection under this Protective Order where the producing party believes in good faith that the material constitutes or discloses highly sensitive business information or items the unrestricted disclosure of which to a requesting party or a receiving party would create a substantial risk of harm, including, but not limited to, the producing party’s planned commercial products and planned licensing agreements. As that term is used herein, “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information and items consist of: (a) highly sensitive information relating to the development of pharmaceutical products; (b) financial or business reports and forecasts including plans, strategies, market analyses, costs, and pricing information; (c) highly sensitive planned licensing agreements; and (d) pending or abandoned patent, trademark, and copyright applications, foreign or domestic, unless published or otherwise publicly available.

8. Access to “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information and items shall be limited strictly to the persons designated as having access to “CONFIDENTIAL” information in Paragraphs 4(a)-4(j) and 4(l), except that, unless otherwise

agreed, no outside counsel who is involved in Competitive Decision-Making as defined in *In re Deutsche Bank*, 605 F.3d 1373 (Fed. Cir. 2010), shall have access to material designated “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.” Persons designated in Paragraph 4(k) (“in-house personnel”) are strictly prohibited from viewing any information designated “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY.”

9. Protected Information will be used solely for the purpose of prosecuting defending, or settling this action, including any appeal and retrial, and will not be used for other purposes including but not limited to patent licensing or for communications, petitioning, litigation, or counseling with or before the U.S. Patent & Trademark Office, FDA, the United States Pharmacopoeia, or any similar foreign or domestic agency.

10. Nothing in this Protective Order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Protected Information if such information:

- (a) Was lawfully in his or her possession prior to receipt under the provisions of this protective order;
- (b) Was or becomes available to the public through no fault of a receiving party;
- (c) Was or is obtained from a source not under an obligation of secrecy to the designating party; or
- (d) Is exempted from the operation of this Protective Order by written consent of the designating party.

11. If any person disputes or challenges the designation of any information as Protected Information based on any ground specified in Subparagraphs (a) through (c) of Paragraph 10, such information shall nevertheless be treated according to its specific designation as Protected

Information (“CONFIDENTIAL,” and/or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY”) in accordance with the provisions of this Order until such designation is removed by Order of the Court or by written consent of the designating party.

**Disclosure of Protected Information**

12. Protected Information shall not be revealed, disclosed, described, summarized, or otherwise communicated or made known to any person or entity, directly or indirectly, other than a Qualified Person (or in case of “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, the person identified in Paragraph 8 (above)), or the party who produced such Protected Information, except as otherwise provided in this Order.

13. A document that contains or reveals protected Information may be shown to any person who authored or previously had access to or knowledge of the document, as demonstrated by the document itself or by foundation testimony during a deposition, hearing, or trial.

14. Protected Information may be disclosed to a witness testifying under oath if the witness is an officer, director, employee, consultant, expert, or representative of the party who produced such Protected Information.

15. Protected Information may be disclosed to a witness testifying under oath if: (a) the witness was formerly an officer, director, employee, consultant, expert, clinical investigator, patent agent or attorney of the party who produced such Protected Information; (b) the Protected Information was in existence during the period of his or her service or employment; and (c) it is reasonable to conclude that the witness was involved in the project to which the Protected Information relates.

16. This Order shall not prevent counsel from examining a witness testifying under oath in a good faith effort to determine whether the witness has discoverable information about the Protected Information.

17. Nothing in this Protective Order shall prevent disclosure of Protected Information if the producing party consents to such disclosure or if the Court, after notice to all parties, orders such disclosure.

18. Counsel desiring to disclose Protected Information to an individual according to Subparagraphs 4(d), 4(f), 4(h), 4(j), 4(k), or any other person according to Subparagraph 4(l) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person. For independent experts or consultants according to Subparagraph 4(d), or for any changes to the individuals identified in Subparagraph 4(k), at least seven (7) days in advance of the proposed disclosure of any Protected Information to that person, counsel, shall serve that person's signed declaration and *curriculum vitae* or resume by facsimile or electronic mail on the other party. The identification of an independent expert or consultant according to Subparagraph 4(d) shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date *curriculum vitae*, any prior or current employments or consultancies for any party within the last five years (except those engagements that are protected from disclosure pursuant to Fed. R. Civ. P. 26), including a list of the cases in which the expert or consultant has testified at deposition, at a hearing, or at a trial within the last four years. A party may object for cause to the proposed disclosure by serving a written objection within seven (7) days after receiving the copy of the signed declaration. Failure to timely object shall operate as a waiver of the objection. If a party objects to the proposed disclosure, the objecting party's Protected Information shall not be disclosed to such person except by Order of the Court or by written consent of the objecting party.



In the even that a motion is made, the objecting party shall have the burden of proving that disclosure should not be made.

19. For the duration of this action and for two years after entry of final judgement from which no appeal may be taken, anyone according to Paragraph 4 who receives another party's Protected Information shall not be involved, directly or indirectly, in the prosecution of any patent application, including reissue, directed to Cyclophosphamide Injection described in NDA No. 212501 or any cyclophosphamide drug product, any method of manufacture of any cyclophosphamide drugs product, or any characterization of or method of characterizing cyclophosphamide forms for intravenous injection. For the avoidance of doubt, "prosecution" as used in this Order does not include engaging formally or informally, or directly or indirectly, in any post-grant proceedings before the Patent Trial and Appeal Board at the U.S. Patent and Trademark Office, including any *Inter Partes* review, post-grant review, or reexamination proceeding.

20. If a party intends to reveal Protected Information of another party during a trial, court appearance, or hearing, which is open to the public, the party intending to reveal such Protected Information shall provide reasonable notice and opportunity to object to the party that produced the Protected Information, unless consent from the party that produced the Protected Information was previously obtained.

21. Should any Protected Information be disclosed, through inadvertence or otherwise, by a receiving party to any person not duly authorized to receive such information under this Protective Order, then the receiving party responsible for such disclosure shall promptly notify opposing counsel of all pertinent facts and make every effort to prevent further unauthorized disclosure, including retrieving all copies of the Protected Information from the unauthorized

recipients) thereof and requesting that each such recipient execute the declaration attached as Exhibit A.

**Identification and Marking of Protected Information**

22. Any document or other tangible thing that contains or reveals Protected Information shall be labeled with the legend “CONFIDENTIAL,” and/or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or a marking of like import. Such marking shall appear on each page of the document that contains Protected Information. For pleadings and discovery requests, such marking need only appear on the first page of the document. Any document or other tangible thing so labelled and the information that it contains or reveals shall be treated in accordance with the provisions of this Protective Order. Any Protected Information not reduced to documentary or physical form or which cannot be conveniently labelled shall be so designated by a party by serving a written notification on the receiving party within a reasonable amount of time after disclosure.

23. When a party initially produces documents for inspection, no marking need be made by the producing party in advance of the inspection. For purposes of the inspection, all documents shall be treated as containing Protected Information. After the receiving party selects specified documents for copying, the producing party shall appropriately mark the copies of the selected documents before they are provided to the receiving party.

24. Only Qualified Persons, the deponent, and the court reporter and videographer shall be allowed to attend any portions of a deposition in which Protected Information is used or elicited from the deponent. The deposition of any witnesses (or any portion of such deposition) that encompasses “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information shall be taken only in the presence of persons who are qualified to have access to such information.

25. Unless otherwise agreed, depositions shall be treated as containing “CONFIDENTIAL” information during the thirty (30) day period following receipt of the transcript. If a party contends that the deposition transcript contains “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, or does not contain Protected Information, that party will be required to affirmatively designate, in writing or on the record, the transcript, or portions of the transcript, as “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or as not containing Protected Information within the thirty (30) day period following receipt of the transcript. If they do not, the transcript shall continue to be treated as containing “CONFIDENTIAL” information.

26. A nonparty to the litigation (e.g., a third party producing information pursuant to subpoena) may designate such information as Protected Information as set forth in Paragraph 22 (above). If so designated, such Protected Information shall be subject to the same restrictions and conditions as information designated by any party as Protected Information. Nothing in this provision shall limit the ability of a party to designate such information produced by a third party as Protected Information.

#### **Inadvertent Failure to Designate**

27. The inadvertent failure by a producing party to designate specific documents or materials as containing Protected Information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. A producing party seeking to designate such documents or materials may do so by giving written notice to the receiving party. Upon notice to the receiving party of such failure to designate, the receiving party shall cooperate to restore the confidentiality of the inadvertently undesignated information. No showing of error, inadvertence, or excusable neglect shall be required for re-designation.

**Storage of Protected Information**

28. The recipient of any “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, that is provided under this Protective Order shall maintain such information in a reasonably secure and safe manner that ensures that access is limited to the persons authorized under this Order, and shall further exercise the same standard of due and proper care with respect to the storage, custody, use, and/or dissemination of such information as is exercised by the recipient with respect to its own proprietary information.

**Data Security**

29. Any person in possession of “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, shall maintain a written information security program that includes reasonable administrative, technical, and physical safeguards designed to protect the security and confidentiality of such “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, protect against any reasonably anticipated threats or hazards to the security of such “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, and protect against unauthorized access to “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information. To the extent a party or person does not have an information security program, they may comply with this provision by having the “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information managed by and/or stored with eDiscovery vendors or claims administrators that maintain such an information security program. If a receiving party or authorized recipient discovers any loss of “CONFIDENTIAL” information, or “HIGHLY

CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, or a breach of security, including any actual or suspected unauthorized access, relating to another party’s “CONFIDENTIAL” information, or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” information, the receiving party or authorized recipient shall: (1) promptly provide written notice to disclosing party of such breach; (2) investigate and make reasonable efforts to remediate the effects of the breach, and provide disclosing party with assurances reasonably satisfactory to disclosing party that such breach shall not recur; and (3) provide sufficient information about the breach that the disclosing party can reasonably ascertain the size and scope of the breach. The receiving party or authorized recipient agrees to cooperate with the producing party or law enforcement in investigating any such security incident. In any event, the receiving party or authorized recipient shall promptly take all necessary and appropriate corrective action to terminate the unauthorized access.

#### **Production of Privileged or Protected Documents**

30. Pursuant to Federal Rule of Evidence 502(d), the production of documents or materials that the producing party thereafter claims to be subject to the attorney-client privilege, work-product immunity, or other protection mandated by local law shall not constitute a waiver of such privilege, immunity, or other protection in this or any other action. After receiving written notice from the producing party that documents or materials subject to the attorney-client privilege, work-product immunity, or other protection have been produced, the receiving party shall not review, copy, or otherwise disseminate the documents or materials, nor shall it disclose their substance. In addition, the receiving party shall return the documents or materials and all copies within five (5) days from receiving notice, or provide written confirmation of the destruction of the original and all copies of the identified documents, including all documents and things

generated by a receiving party which contain information derived from the returned/destroyed materials. The receiving party shall not utilize the information contained in the returned/destroyed documents or materials for any purpose, or disseminate or transmit such information.

(a) If the receiving party wishes to contest that any such document or thing is protected by the attorney-client privilege, work-product immunity, or other protection mandated by local law, the receiving party shall so notify the producing party in writing when the document or thing is returned to the producing party (“Notice of Designation”).

(b) Within five (5) days after receiving a Notice of Designation, the producing party shall provide to the receiving party for each such document or thing a description of the basis for the claim of privilege, immunity, or other protection.

(c) Within five (5) days after receiving such description, the receiving party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed. In any such motion to compel production of the returned/destroyed document, the receiving party shall not rely upon in any manner or assert as a ground for ordering production the fact, circumstances, or contents of the production. Any such motion shall be filed under seal, as permitted by the Court.

(d) The parties may stipulate to extend the time periods set forth in (b) and (c) above.

(e) Nothing in this Order overrides any attorney’s ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the disclosing party that such materials have been produced.

(f) The disclosing party retains the burden—upon challenge pursuant to Subparagraph (c) above—of establishing the privileged or protected nature of the information in question.

(g) Nothing in this order limits the right of any party to petition the Court for an *in camera* review.

(h) This Order does not preclude a party from voluntarily waiving the attorney-client privilege or work-product protection. The provisions of Federal Rules of Evidence 502(a) apply when the disclosing party uses or indicates that it may use information produced under this order to support a claim or defense.

(i) Under this Order, the provisions of Federal Rule of Evidence 502(b) are inapplicable.

#### **Challenges to Protected Information Designation**

31. A party shall not be obligated to challenge the propriety of a Protected Information designation at the time of production of the designated materials, and a failure to do so shall not preclude a subsequent challenge thereto. In the event that a party disagrees at any time with a Protected Information designation made by another party, the parties shall make a good faith attempt to resolve the dispute on an informal basis. If the parties cannot resolve the dispute, the objecting party may seek appropriate relief from the Court, and the designating party shall have the burden of proving that its Protected Information designation is proper.

### **Filing of Protected Information**

32. If a party deems it necessary to submit Protected Information to the Court, the party shall file or designate such information under seal in accordance with District of Delaware Local Rule 5.1.3., and nothing in this Order shall preclude the producing party from requesting that the Court seal that party's Protected Information. The sealing of the information shall remain in effect until further order of the Court. A second copy of any pleading or paper specifically intended for review by the Court may be hand-delivered to the Court's chambers appropriately marked, in order to assure that the same is brought promptly to the Court's attention.

33. The Clerk of the Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court that has been designated, in whole or in part, as containing or revealing Protected Information.

34. Nothing in this Order shall prevent a party from using any document, material, or other information that is designated as Protected Information under this Order at a hearing, trial, or other court proceeding in this action, provided such use is otherwise consistent with the terms of this Order, and such document, material, or other information shall not lose its confidential status through such use. The parties shall take all steps permitted by the Court and reasonably required to protect the confidentiality of such designated information during such use.

### **Advice to Clients**

35. Nothing in this Protective Order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to this action, and, in the course thereof, referring to or relying upon his or her examination of Protected Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any



Protected Information if such disclosure would be contrary to the provisions of this Protective Order.

**Discoverability of Expert Materials**

36. Discovery of communications between counsel and any independent expert or consultant retained or specifically employed by that counsel shall be limited to factual information, assumptions provided by counsel and relied upon by the expert, analyses, documents, expert compensation, and data considered or relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all other communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communication relating thereto, shall be deemed exempt from discovery and use at trial.

**Third-Party Requests**

37. If any third party requests the production of any Protected Information, including but not limited to a request by subpoena, the receiving party in possession of such Protected Information must:

- (a) Notify the producing party within seven (7) days of receiving the request;
- and
- (b) Take all lawful steps necessary to assert (or permit the Producing Party to assert) all applicable protections, including but not limited to:
  - (i) Permitting the producing party a reasonable opportunity to intervene and be heard, and
  - (ii) Defending the asserted rights, privileges, and immunities if the producing party cannot be heard.

### **Other Proceedings**

38. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

### **Miscellaneous**

39. No party shall be responsible to another party for any use made of information that was produced and not designated as Protected Information.

40. Documents and things produced or made available for inspection may be subject to redaction, in good faith by the Producing Party, or information that is neither relevant to the subject of this Action nor reasonably calculated to lead to the discovery of admissible evidence, or is subject to the attorney-client privilege or work-product immunity. Any such redaction shall be clearly labelled. No redaction for relevance or non-responsiveness shall be made that obscures or otherwise impacts those relevant or responsive portions of a document, including as to any context necessary to a complete understanding, presentation, or calculation of any relevant or responsive portions. All documents redacted based on attorney-client privilege or work-product immunity shall be listed alongside their corresponding Bates number in a privilege log stating the basis for such redaction.

41. Nothing here shall prevent the parties from redacting personally identifying information or other information protected under Swiss, German, or UK privacy law, the General

Data Protection Regulation, or other foreign laws and regulations. The parties recognize that certain witnesses may be subject to laws concerning data privacy, data secrecy, or cross-border data transfer restrictions that require protections or limitations beyond those described herein. The parties shall work in good faith to address such issues as they arise and to abide by relevant foreign laws and regulations.

42. When the inadvertent or mistaken disclosure of any information contained in any document that the producing party believes is non-responsive is discovered by the producing party and brought to the attention of the receiving party, the producing party shall promptly produce a properly redacted replacement version of said document to the receiving party. Upon receipt of the replacement version, the receiving party shall immediately return and/or destroy all copies of the original version of said document, and confirm in writing to the producing party that it has done so.

43. Any production of documents and ESI located abroad, in particular in Europe and Switzerland, will need to comply with local laws, including laws concerning cross-border data transfer, data privacy, and data secrecy protections. Further, there are restrictions on the taking of depositions outside of the United States. Should any such depositions be needed, the parties will meet and confer to try and resolve any issues that might arise.

44. Nothing in this Protective Order shall be deemed a concession that foreign law provisions govern in this case or prejudice the right of any party to challenge the appropriateness of any confidentiality designations made under this Protective Order, including as Protected Data.

45. Nothing in this Protective Order shall prejudice the right of any party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

46. Nothing in this Protective Order shall prejudice the right of any party to seek at any time a further order modifying this Protective Order.

47. Nothing in this Protective Order shall prejudice the right of any party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any Protected Information.

48. In the event that a new party is added, substituted, or brought in, this Protective Order will be binding on and inure the benefit of the new party, along with the corresponding obligations on the new party to maintain the confidentiality of the Protected Information, subject to the right of the new party to seek relief from or modification of this Protective Order.

49. Nonparties who produce information in this Action may avail themselves of the provisions of this Protective Order.

50. Within ninety (90) days after the termination of this Action (including any appeals), each document and each other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information shall be either: (a) returned to the attorney of record for the producing party; or (b) destroyed with a representation of such destruction being made to the attorney of record for the producing party.

51. Within ninety (90) days after any counsel has withdrawn or otherwise been terminated as counsel of record, said counsel shall likewise return or destroy each document and each other tangible thing in their possession that contains or reveals Protected Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information.

52. Notwithstanding the foregoing, outside counsel and in-house legal representatives may maintain each of the following: each paper filed with the Court together with any exhibits thereto, each deposition transcript together with the exhibits marked at the deposition, each expert report together with any exhibits thereto, all written discovery and responses thereto, each demonstrative used at trial or any other hearing, each trial or hearing transcript, each exhibit used at trial, each item of correspondence, and all drafts, memoranda, and other documents constituting work-product which were based upon or which include Protected Information, so long as the terms of this Protective Order will continue to govern any such retained materials and provided that information protected by data privacy will not be retained. In the event that outside counsel and in-house legal representatives maintain such documents, they shall not disclose material containing any Protected Information to another party or third party absent subpoena or court order. Outside counsel and in-house legal representatives likewise need not purge their email, document management systems, or back-up storage media, provided, however, that any Protected Information contained in such documents retained by counsel shall remain subject to the protections of this Protective Order. No person of receiving party is obligated to return or destroy Protected Information contained on electronic backup tapes or other archival media, which should be treated in accordance with standard retention policies. However, the extent that any material is accessed from backup storage media, information protected by data privacy obligations shall be destroyed or returned and legal hold obligations shall be periodically reviewed for necessity and proportionality and information protected by data privacy obligations shall not be retained in perpetuity.

53. The provisions of this Protective Order shall survive and remain in full force and effect after the termination of this Action (including any appeals). This Court shall retain

jurisdiction even after termination of this litigation to enforce this Protective Order and make such amendments, modifications, deletions, and additions to this Protective Order as the Court may from time to time deem appropriate.

54. This Protective Order may be amended as need may arise by written agreement of the parties, subject to Court approval.

Dated: December 17, 2024

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Daniel A. Taylor

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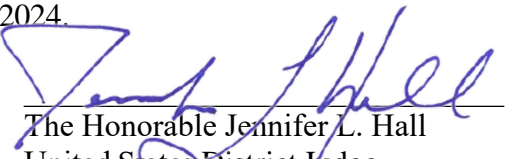
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Hetero USA, Inc., Hetero Labs Ltd., and  
Hetero Labs Ltd. Unit-VI*

SO ORDERED this 19<sup>th</sup> day of December, 2024.

  
The Honorable Jennifer L. Hall  
United States District Judge

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD.,  
and HETERO LABS LTD. UNIT-VI,

Defendants.

C.A. No. 24-1025-JLH

**AGREEMENT TO BE BOUND**

I, \_\_\_\_\_, declare and state under penalty of perjury that:

1. My address is \_\_\_\_\_.

2. My present employer is \_\_\_\_\_, and the address of  
my present employer is \_\_\_\_\_

\_\_\_\_\_.

3. My present occupation or job description is \_\_\_\_\_

\_\_\_\_\_.

4. I have received a copy of the Stipulated Protective Order in this Action, which  
order was entered on \_\_\_\_\_.

5. I have carefully read and understand all of the provisions of the Stipulated  
Protective Order.

6. I will comply with all of the provisions of the Stipulated Protective Order.

7. I will hold in confidence, will not disclose to anyone not qualified under the Stipulated Protective Order, and will use only for purposes of this Action, any Protected Information that is supplied to me.

8. At the termination of this Action or any time requested by counsel for the party by whom I am employed, I will return each document and each other tangible thing that discloses or reveals any Protected Information to the attorney who provided such document or other tangible thing to me. Moreover, I will deliver any copies, abstracts, summaries, notes, or other records regarding the contents of any Protected Information to the attorney who provided such Protected Information to me.

9. I understand that if I violate the provisions of the Stipulated Protective Order, I will be in violation of a Court Order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages.

10. I hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of enforcement of the Stipulated Protective Order.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Signature